In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-1298V UNPUBLISHED

FRANKLIN GALLO,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 5, 2019

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.

Julia Marter Collison, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

On August 27, 2018, Franklin Gallo filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,² (the "Vaccine Act"). Petitioner alleges that he suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of a tetanus, diphtheria, acellular pertussis ("Tdap") vaccine administered on September 5, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, <u>100 Stat. 3755</u>. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of <u>42 U.S.C. § 300aa (2012)</u>.

For the reasons discussed below, I find that the Tdap vaccine alleged as causal was administered in Petitioner's left deltoid on September 5, 2017.

I. Relevant Procedural History

After filing his petition, Petitioner filed medical records, an affidavit, and a Statement of Completion. ECF Nos. 7, 12-14. At the initial status conference, it was noted that Petitioner's affidavit references communications from Petitioner to the Veterans Administration regarding his previous attempts to correct his September 5, 2017 vaccination record. ECF No. 15. Following the initial status conference, Petitioner was ordered to file any associated records in connection with these communications. *Id.* Additionally, Respondent was ordered to file a status report indicating how he intends to proceed in this case. *Id.* On March 21, 2019, Petitioner filed records from the Veterans Administration regarding his attempts to correct his vaccination record. ECF No. 16.

On June 13, 2019, Respondent filed a status report and Motion to Dismiss ("Res. Motion"). ECF Nos. 19-20. Respondent asserted that Petitioner's claim concerns a vaccine not covered by the Vaccine Act. Res. Motion at 1. Specifically, Respondent observed that Petitioner alleged that he suffered a SIRVA after receiving a Tdap vaccination in his left shoulder on September 5, 2017. *Id.* However, Respondent noted that Petitioner's vaccination record documents that Petitioner was administered a Tdap vaccine in his *right* deltoid, and a non-covered Pneumovax vaccine in his left deltoid. *Id.* at 1-2. Additionally, Respondent cited a letter addressed to Petitioner from the Veterans Administration noting that Petitioner's vaccination record is accurate in its current form. *Id.* at 2. Based on this evidence, Respondent argued that Petitioner's claim must be dismissed due to lack of jurisdiction or for failure to state a claim on which relief can be granted. *Id.* at 2-3.

Petitioner filed a Response to Respondent's Motion to Dismiss ("Pet. Response") on June 27, 2019, addressing Respondent's arguments and asserting that Petitioner has provided sufficient evidence to establish that the Tdap vaccine was administered in his left deltoid. <u>ECF No. 22</u>. Petitioner cited numerous medical records in support of his position and contended that there is at least a genuine issue of material fact regarding the site of Petitioner's Tdap vaccination. Pet. Response at 2-4. Respondent did not file a reply.

On July 31, 2019, an order was issued denying Respondent's Motion to Dismiss because it was found that there is a genuine factual dispute as to the site of Petitioner's September 5, 2017 Tdap vaccination. <u>ECF No. 23</u>. The parties were therefore ordered to file any relevant evidence they wished to have considered regarding the site of Petitioner's vaccination. *Id.* The parties were informed that a fact ruling would subsequently be issued regarding the site of Petitioner's vaccination. *Id.*

On August 28, 2019, Respondent filed a status report ("Res. Status Report") in which he reiterated his previous position that Petitioner failed to establish that he received

a Tdap vaccine in his left arm on September 5, 2017. Res. Status Report at 1. Initially, Respondent asserted that Petitioner had not provided evidence that he has the necessary qualifications—e.g., medical background or training—to distinguish between the Tdap and Pneumovax vaccines, which are both administered intramuscularly. *Id.* at 1-2. Furthermore, Respondent noted that Petitioner's post-vaccination statements regarding the situs of his Tdap vaccination are based on his recollection alone. *Id.* at 2. Because these later references are "not contemporaneous documentation by vaccine administrators," Respondent argued that they "deserve little weight with regard to establishing the site of vaccination." *Id.* Finally, Respondent observed that this case involves a vaccination record that is contrary to Petitioner's claims, plus a subsequent letter from the Veterans Administration noting that Petitioner's vaccination record is accurate in its current form. *Id.* at 2-3. Respondent argued that Petitioner has not established that his own recollection is more reliable than the aforementioned records regarding the site of administration. *Id.*

On August 30, 2019, Petitioner filed additional medical records and affidavits from four acquaintances. <u>ECF No. 25</u>. This matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the Tdap vaccination alleged as causal in the injured left arm.

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); see also Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

For the reasons discussed below, I find that the Tdap vaccine alleged as causal was administered in Petitioner's left deltoid on September 5, 2017, as Petitioner alleges. I make this finding after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I base the finding on the following evidence:

• On September 5, 2017, Petitioner presented to the Miami Veterans Affairs Medical Center ("VA Medical Center") for a health maintenance appointment, medication review, and annual physical. Petitioner's Exhibit ("Pet. Ex.") 1 at 1. The associated medical record does document that Petitioner "requested and received" a Tdap vaccination intramuscularly in the right deltoid. Id. at 4. The medical record additionally reflects that Petitioner "received" a Pneumovax vaccination intramuscularly in the left deltoid.³ Id.

³ Petitioner sent an amendment request dated October 18, 2018 to the VA Medical Center to correct his September 5, 2017 medical record to reflect that the Tdap vaccine was administered in his left deltoid and

- One day later, on September 6, 2017, Petitioner called the VA Medical Center to report pain at the "Tetanus shot site," which he described as being on his left arm. Pet. Ex. 2 at 52.
- On October 5, 2017, Petitioner presented to Holy Cross Medical Group with complaints of left shoulder pain. Pet. Ex. 3 at 7. Petitioner stated that he had recently been administered a tetanus vaccine and had experienced pain since that time. Id.
- On October 24, 2017, Petitioner returned to the VA Medical Center. Petitioner reported persistent left deltoid discomfort that started more than one month prior following a Tdap vaccination. Pet. Ex. 2 at 46.
- On February 15, 2018, Petitioner presented to Ali A. Harake MDPA Practice complaining of a five-month history of pain following the administration of a tetanus vaccination in his left deltoid. Pet. Ex. 5 at 3.
- On March 15, 2018, Petitioner presented to Cleveland Clinic for treatment of left shoulder pain. Pet. Ex. 6 at 64. Petitioner reported that he had received a tetanus vaccination in September and soon thereafter developed shoulder pain. *Id*.
- On August 28, 2018, Petitioner returned to Holy Cross Medical Group. Pet. Ex. 3 at 21. Petitioner reported that he continued to have left shoulder pain following a tetanus injection. *Id*.
- On December 6, 2018, Petitioner returned to Holy Cross Medical Group. Pet. Ex. 8 at 1. Petitioner was noted to have a "history of worsening left shoulder pain, starting after he received a tetanus shot in the left shoulder over 1 year ago." Id.
- On March 6, 2019, Petitioner filed a detailed affidavit providing additional information regarding the September 5, 2017 medical appointment and his subsequent treatment. Pet. Ex. 9. At the medical appointment, Petitioner stated that he recalled "being alerted that the tetanus shot was about to be administered in the left arm (being right handed)." Id. at ¶ 2. Petitioner averred that he had suffered an adverse reaction to a tetanus-diphtheria vaccination as a child, which led to significant medical complications. Id. Petitioner stated that this childhood experience was "burned in [his] memory." Id. Accordingly, Petitioner asserted that he knew the arm in which the Tdap vaccine was being administered during the September 5, 2017 medical appointment. Id.

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that the Pneumovax vaccine was administered in his right deltoid. Pet. Ex. 10 at 1. In a reply correspondence dated November 2, 2018, the Veterans Administration denied Petitioner's request, noting that Petitioner's vaccination record is accurate in its current form. *Id.* at 4.

• On August 30, 2019, Petitioner filed an affidavit from Arlan R. Best, an acquaintance. Pet. Ex. 13. Mr. Best averred that Petitioner called him on the evening of September 5, 2017 to complain that "he was experiencing excruciating pain in his left arm where he had received a tetanus shot." Id. at ¶ 2. Petitioner also filed affidavits from three other acquaintances on August 30, 2019, who similarly recalled that Petitioner attributed his left arm symptoms to a tetanus injection in the days and weeks following his September 5, 2017 vaccination. Pet. Exs. 12, 14-15.

In making the above finding regarding situs, I note that special masters have found that vaccine administration occurred, or was incorrectly recorded, even in the absence of direct documentation, based upon other medical records and/or witness testimony. More broadly, witness testimony can be used to overcome the presumption of accuracy afforded to contemporaneous medical records, if the testimony is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

Based upon my review of the record, I find that Petitioner has established by preponderant evidence that he received the Tdap vaccine in his left arm. There is no doubt that the primary evidence of vaccination documents Mr. Gallo's right arm as the situs of the Tdap vaccination. In many cases, such a document would resolve the dispute. But I find that this entry specifying administration is rebutted by Petitioner's contemporaneous medical records, as well as his own recollection of the actual situs, which together are sufficiently "clear, cogent, and compelling" to overcome the available vaccination record.

In particular, Petitioner has provided a reasonable explanation for why he would have recalled the arm in which the Tdap vaccine was administered. As described above, Petitioner had suffered an adverse reaction to a tetanus-diphtheria vaccination as a child, which led to significant medical complications.

Petitioner requested that the Tdap vaccine be administered in his left arm because it is his nondominant arm. Pet. Ex. 9 at ¶ 2. Moreover, Petitioner stated in his affidavit that he was informed, at the time of the vaccination, that the Tdap vaccine was about to be administered in his left arm. *Id.* Accordingly, Petitioner asserted that he was cognizant of the arm in which the Tdap vaccine was being administered *during* the September 5, 2017 medical appointment. *Id.*

I note that the vaccination record contains differing entries regarding the administration of the Tdap and Pneumovax vaccines. Under the Tdap vaccine, Petitioner was noted to have "requested and received [the vaccine] intramuscular[ly] in the right deltoid." Pet. Ex. 1 at 4 (emphasis added). Under the Pneumovax vaccine, however, Petitioner was noted only to have "received [the vaccine] [intramuscularly] today in Left Deltoid." Id. (emphasis added).

I find the use of the phrase "requested and received" in describing one vaccine (the Tdap), but not the other (Pneumovax) significant under the circumstances. Petitioner has persuasively established he had a reasonable concern in specifying the arm for

administration of the Tdap vaccine. The inclusion of both "requested" and "received" under the Tdap vaccine suggests that Petitioner requested the arm in which the Tdap (but not Pneumovax) vaccine would be administered. Given that Petitioner is right-handed and has alleged a prior adverse reaction to a tetanus vaccine, I find the evidence supports the conclusion that Petitioner requested that the Tdap vaccine be administered in his left nondominant arm, but that the request and subsequent administration were incorrectly recorded in his medical records.

Respondent has argued that Petitioner has not provided evidence that he has qualifications—e.g., medical background or training—to distinguish between the Tdap and Pneumovax vaccines, which are both administered intramuscularly. Res. Status Report. at 1-2. I find, however, that a lack of additional qualifications is not dispositive in this case. Indeed, as indicated above, Petitioner stated in his affidavit that he was informed, at the time of the vaccination, that the Tdap vaccine was about to be administered in his left arm. Pet. Ex. 9 at ¶ 2. Moreover, Petitioner's contemporaneous medical records—including from the day following the vaccination—specifically tie Petitioner's left shoulder symptoms to the Tdap vaccination and are thus corroborative of his allegations.

The facts of this case present a close call on the issue of situs. Based upon my review of the entire record, however, I find there is preponderant evidence to establish that the Tdap vaccine alleged as causal in this case was administered to Petitioner in the left deltoid on September 5, 2017.

V. Scheduling Order

Respondent shall file a status report, by no later than <u>Tuesday</u>, <u>January 21, 2020</u>, indicating whether he is interested in exploring an informal resolution of Petitioner's claim.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master